

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF APPEALS AND INTERFERENCES**

In re Patent Application of:
Lawrence W. Cosenza

Application No.: 10/735,203

Confirmation No.: 2593

Filed: December 12, 2003

Art Unit: 1633

For: SACROMASTIGOPHORIC THERAPEUTIC
AGENT DELIVERY SYSTEM

Examiner: Anne Marie Sabrina
Wehbe

APPELLANT'S REPLY BRIEF UNDER 37 CFR §41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 37 C.F.R. 41.41, this reply brief is filed within two months of the Examiner's Answer.

RESPONSE TO EXAMINER'S ARGUMENTS

I. Summary of the Claimed Subject Matter is Proper.

Appellant affirms that in response to a restriction requirement that an election of species was made without traverse to elect as a therapeutic agent a "drug or prodrug", Hpr as the lytic factor, and a sacromastigoporic organism being a trypanosome, as noted in the Examiner's Answer, Section 5, spanning pages 2-3. While this had implications in the scope of the examination of the claims 1, 2, 4, 7, 8, 11, and 41, Appellant notes that with a reversal of the outstanding rejection as to claim 1 and 11 as linking claims, rejoinder of other claims was noted

as a matter of right (Paper No. 20060821, page 4) and as such the scope of the Summary of the Claims is submitted to be proper.

II. The teaching as to HPr sequences provided in the specification satisfies the written description requirement.

The Examiner's Answer notes that human Hpr is provided in the specification in satisfaction of the written description requirement. While the rejection is premised on 200+ primates and uncertainty as the nature of full length Hpr across other primate species, Appellant made of record remarks to suggest that one of skill in the art would appreciate that the genus is minute (limited to humans, gorillas, and chimpanzees) and homology therebetween is high. As the determination is factual and written description as to initially filed claims is presumed, reversal of this rejection is requested. The subsequently dated reference mentioned in the remarks made of record was not, and could not be provided to show the status of the art at the time of filing, but rather to refute the contention that this is a statement made of record that the genus is large and lacks homology within the genus. Appellant claimed and disclosed the genus in question, HPr to a degree as known at the time of filing. As this is factually based determination and the Examiner failed to show that there is either a large number of primates carrying the gene on question or that the gene in question has meaningful variability and as such has failed to carry the burden that the claims as filed do not satisfy the written description requirements, namely that full length Hpr in primates varies from that provided in SEQ ID. No: 28. this is important to the reversal of this rejection.

Appellant position is consistent with the REVISED INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIAL (www.uspto.gov/web/offices/pac/writtendesc.pdf). While these Guidelines are not binding, in particular Example 8 of these Guidelines suggest a situation to the Board in which a finding of

satisfaction of the written description requirements should be found. As the subject matter of the claims subject to appeal was present in the claims as filed (see original claim 5 relating to Hpr), the Courts have held that written description of claims as originally filed is presumed to exist. *In re Gardner*, 178 USPQ 149 (CCPA 1973).

A complete nucleic acid sequence for Hpr in recombinant form is presented in the instant application as Seq. ID No. 28. (p. 34, lines 16-17; Figures 10, and 11) Therefore, the instant application provides sufficient written description of recombinant Hpr.

III. The teaching as to HPr sequences provided in the specification satisfies the written description requirement

The Examiner's Answer frames enablement in terms of functional recitations that are not applicable to the system (compositional) claims 1, 2, 4, 7, 8, and 11. Appellant submits that enablement of these claims is satisfied by teaching the specification teaching as to how the construct is formed. Those arguments as the function of the composition embodied the Examiner's Answer are relevant to claim 41, yet as to the other claims subject of this appeal, it is submitted that the relevant question is "Would one of ordinary skill in the art be able to make the invention as claimed in claims 1, 2, 4, 7, 8, and 11 based on the specification without undue experimentation?" Appellant submits that that answer is "Yes", as Figure 1 provides an enabling construct for the claimed system, specifically including a construct containing a gene encoding Hpr is under the control of a Tet inducible promoter (PARP*). As to claim 41, Appellant relies on the remarks of record to show enablement.

Conclusion

In summary, the specification fully describes the invention and enables a person having

ordinary skill in the art to make and use the invention without undue experimentation by providing numerous working examples and a thorough description of all elements in the claims demonstrating that Appellant had full possession of the invention at the time of filing.

Accordingly, the rejections under 35 U.S.C. §112, first paragraph as to written description and enablement with regard to the pending claims should be REVERSED.

The Director is hereby authorized to charge any fees, which may be required, or credit any overpayment, to Deposit Account Number 07-1180.

Date: 1 March 1, 2010

Respectfully submitted,

By: /Avery N. Goldstein, Ph.D./
Avery N. Goldstein
Registration No. 39,204
Gifford, Krass, Sprinkle,
Anderson & Citkowski, P.C.
2701 Troy Center Drive, Suite 330
P.O. Box 7021
Troy, MI 48007-7021
(248) 647-6000
Attorney for Appellant